

Notice of Allowability

Application No.

10/824,828

Applicant(s)

THOMAE ET AL.

Examiner

Art Unit

Malgorzata A. Walicka

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Feb. 1, 2007.
2. ☒ The allowed claim(s) is/are 1,7,9,11,13 and 20-23.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 02/02/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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The Amendment and Reply filed Feb. 1, 2007 are acknowledged. Claims 2, 14 and 19 have been cancelled. New claims 20-23 have been added, and claims 1, 7, 9, 11 and 13 have been amended. Claims 1, 3-13, 15-18, and 20-23 are pending; claims 1, 7, 9, 11, 13 and 20-23 in their entirety, related to DNA encoding the variant of SEQ ID NO: 5 having substituted positions 173, 287 and 306 are under examination. Claims 3, -6, 8, 10, 12, 15-18 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

DETAIL ACTION

All objections or rejections made in the Office action of Nov. 1, 2006 (previous action) that are not repeated herein are moot or withdrawn.

35 USC section 112, second paragraph issues

The amended claims 1, 7, 9, 11 and new claims 20-23 are not rejected under 35 U.S.C. 112, because the amendments to the claims and Applicants' statement on page 9 of 12 of REMARKS, second paragraph, which is quoted below.

"Applicants note that nucleic acid molecule "consisting essentially of" the recited variant sequence have the basic and novel characteristics that they are able to distinguish, based upon hybridization, a nucleic acid having a sequence that does not contain the variant (e.g., the wild type sequence). Applicants further note that the claimed nucleic acid molecules can include additional sequences or labels (e.g., a fluorescent label as disclosed at page 23, lines 6-7

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of Applicants' specification), provided that such additions do not affect the basic and novel characteristic of the nucleic acid molecules."

The statement clarifies the fact that the claims are directed to the fragments of the allelic variant of SEQ ID NO: 1 disclosed by Applicants, or probes containing said fragments and that both of them may be used for probing allelic variants of the enzyme encoded by SEQ ID NO: 1.

35 USC section 112, first paragraph issues

Lack of written description

The amendments and Applicants' statement quoted above, overcome the rejections for lack of written description of structure and function made in the previous action.

Scope of enablement

The amendment and Applicants' statement from page 9/12 of REMARKS quoted above overcome the rejection made under this paragraph in the previous action.

35 USC 102

Rejection of claim 13 under 35 U.S.C. 102(b) as being anticipated by Lin S. et al, (A novel S-adenosyl-L-methionine:arsenic (III) methyltransferase from rat liver cytosol, J. Biol. Chem. 2002, 277, pp. 10795-10803, enclosed in IDS), and Strausberg R. L. et al. (Generation and initial analysis of more than 15,000 full-length human and mouse

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cDNA sequences, Proc. Natl. Acad. Sci. USA, 2002, 99, pp. 16899-16903) is withdrawn, because the claim has been amended.

Examiner's amendment

1. Please cancel claims 3-6, 8, 10, 12, 15-18 directed to a non-elected invention.
2. Please amend claim 13 to read:
 13. A isolated nucleic acid encoding an ASMT polypeptide, wherein said polypeptide consists of [comprises] an ASMT amino acids sequence variant relative to the amino acid sequences of SEQ ID NO: 5, and wherein said amino acid sequence variant is a tryptophan at residue 173, a threonine at residue 287, or an isoleucine at residue 306.

Authorization for this examiner's amendment was given in a telephone interview with Applicants' representative Elizabeth N. Kaytor on April 17, 2007.

Conclusion

Claims 1, 7, 9, 11, 13 and 20-23 are allowed. The following is examiner's reasons for allowance. Applicants are the first to disclose alloenzymes of human S-adenosyl-L-methionine:arsenic (III) methyltransferase of SEQ ID NO: 5, their encoding DNA molecules and the sequences that may be used as probes specific for allelic variants. The sequences may be also used for determining a risk of an individual for toxicity from acute or chronic arsenic exposure.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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